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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/509,673	10/08/2004	Katsuyoshi Nagao	040520	6132

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EXAMINER	
WIEST, PHILIP R	

ART UNIT	PAPER NUMBER
3761	

MAIL DATE	DELIVERY MODE
03/18/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/509,673	NAGAO ET AL.	
	Examiner	Art Unit	
	Phil Wiest	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 January 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3 and 5-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *1,3 and 5-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *08 October 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 9/7/07.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1/23/08 has been entered.

Response to Amendment

2. In the reply filed 1/23/08, applicant amended claims 1, 3, 6, 11, and 19, and added new claim 25. Claims 1, 3, and 5-25 are currently pending.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 1, 3, 5, 6, 9-12, 14-20, and 22-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barney (US 5,462,526) in view of Larkin (US 4,602,910).

5. With respect to Claims 1, 3, 5, 6, 9-12, 17-20, and 25 Barney discloses a multiple-chamber medical container comprising a container body having multiple chambers (12, 34, 22) separated by partitioning seals to separate the chambers from one another, a medicinal outlet portion 40 for discharging the chambers, and an openable additional small container formed of sheet material located within a chamber and having a medicament therein. The partitioning seal portion is formed by separably bonding opposing inner wall surfaces of the container body. The small container is structured to open in response to external forces and has a bonded portion 64 bonded to the container body. The small container is located almost directly next to the partitioning seal (figures 1 and 2), and is heat sealed such that it opens in response to external force. Furthermore, all the sheets in the device of Larkin are multilayer polymeric films.

Barney, however, does not disclose that a separably bonded portion 70 of the small container is formed by bonding opposing outer surfaces of the sheet material, wherein the opposing outer surfaces are opposed to the opposing inner surfaces of the container body in the vicinity of the partitioning seal portion.

Larkin discloses a medical container comprising a large chamber 10 surrounding a small medicament container 36, wherein the seal 43 between the chambers is formed by heat sealing the layers such that they are separably bonded. The sheets are made of multilayer film (see Figure 6). The outer surfaces of the small container are bonded to the inner surfaces of the container, such that the small container's seal becomes delaminated when pressure is applied (see Figures 4 and 5). The use of this sealing

technique allows a weaker seal to be formed between the inner sheets than between the inner and outer sheets, therefore preventing the container walls from breaking by causing the inner seal to break first (Column 4, Lines 9-22). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the multiple-chamber medical container of Barney with the delaminating sheet configuration of Larkin in order to allow the inner seal to break at a lower pressure than the outer seals, thereby allowing fluid communication to be established without risking damage to the other seals in the container.

6. With respect to Claims 14 and 22, Barney discloses an outlet port 40, but does not specifically state that the port comprises a sealing member. However, the figures disclose that the outlet port appears to be a Luer fitting or some other type of port that comprises a valve. Furthermore, Barney discloses that the outlet port is for dispensing the contents of the container *subsequent to* mixing of the medicament (Column 4, Lines 52-61). Therefore, it is the examiner's opinion that Barney provides sufficient motivation to mrovide a valve or sealing means at the outlet, such that the container does not leak fluid until a proper fluid connection is attached.

7. With respect to claims 15 and 23, Barney discloses a plurality of chambers containing diluents and medicaments, but does not specifically disclose the type of medicament used. Larkin discloses a medical container comprising a large container and a small container, said small container holding a medicament that mixes with the

fluid in the large container. Larkin further discloses that the medicament may be an antibiotic. The use of powdered antibiotic medicaments is extremely common in the art because it allows them to not be mixed with fluid until necessary. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the device of Barney with the use of an antibiotic medicament of Larkin in order to provide a means for mixing antibiotic solution.

8. With respect to Claims 16 and 24, the bag of Barney in view of Larkin is fully capable of being placed inside a bag and arranged in any position. If applicant amends the claims to add structure to the bag, the examiner reserves the right to impose a restriction requirement between the bag and the container.

9. Claims 7 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barney in view of Larkin, and further in view of Inoue (US 5,423,421). Barney and Larkin disclose the device substantially as claimed, but do not specifically disclose that the seal comprises a plurality of bonded parts arranged with at least one non-bonded part therebetween. Inoue discloses a multichamber container for mixing medical fluids, wherein a small container is is fluidly connected to a large container by a seperable bonded section. The bonded section is configured such that it becomes delaminated when sufficient pressure is applied (see figure 4). Furthermore, the bonded section comprises a non-bonded portion 9 in the center of the bonded portion. This configuration reduces the amount of sealing that is performed, thereby reducing the

strength of the seal to make it easier to open, and eliminates the likelihood that the sealing operation will thermally degrade the medicinal preparations accommodated in the chambers (Column 4, Line 63 through Column 5, Line 37). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the medicament mixing device of Barney and Larkin with the unsealed portion of the bonded section of Inoue in order improve the breakability of the seal and prevent heat damage to the medicaments stored within the device.

10. Claims 13 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barney in view of Larkin, and further in view of Becker (US 6,319,243). Barney discloses the device substantially as claimed, but does not specifically disclose that the small container is disposed in the same chamber as the outlet portion. Becker discloses a multichamber container for mixing medicaments, wherein a plurtality of breakable seals (18, 20) are positioned between the chambers, therefore allowing selective mixing of the chambers (see Figures 1 and 2). Becker further discloses a plurality of outlets (31, 32, 34) (one in each chamber), such that fluid may be selectively drained from any of the chambers. This would allow, for example, fluids from two of the three chambers to be nixed together and drained, without mixing the fluid with the third chamber. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the medical fluid mizing device of Barney and Larkin with Becker's use of a plurality of fluid outlets (i.e. one in each chamber), such that fluids could be mixed and drained in a variety of ways. It may not always be desirable to mix

all the medicaments together, and placing an outlet in the same chamber as the smaller chamber would allow those fluids to be selectively mixed.

Response to Arguments

11. Applicant's arguments with respect to claims 1, 3, and 5-24 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phil Wiest whose telephone number is (571)272-3235. The examiner can normally be reached on 8:30am-5pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Phil Wiest/
Examiner, Art Unit 3761

/Tatyana Zalukaeva/
Supervisory Patent Examiner, Art Unit 3761